DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 14 2007

Re: S8 Over-the-Wire System

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the following applications for patent term extension filed by Medtronic Vascular, under 35 U.S.C. § 156. The patents claim S8 Over-the-Wire System, PMA P030009.

Product	Patent Number	Docket Number
S8 Over-the-Wire System	5,292,331	2004E-0304
S8 Over-the-Wire System	5,800,509	2004E-0300
S8 Over-the-Wire System	5,836,965	2004E-0306
S8 Over-the-Wire System	5,879,382	2004E-0303
S8 Over-the-Wire System	5,891,190	2004E-0301
S8 Over-the-Wire System	6,159,229	2006E-0206
S8 Over-the-Wire System	6,309,402	2004E-0302
S8 Over-the-Wire System	6,344,053	2004E-0426

In the February 23, 2007, issue of the Federal Register (72 Fed. Reg. 8182), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before August 22, 2007, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Medtronic Vascular
IP Legal Department
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Santa Rosa, CA 95403